

Laptop Name - DRL0098686

Spector Client: installed and active since 4/22/10

SUBJECT: Robert C. Smith (RCS)
Medical Officer
WO66 RM0319G HFZ-470
CDRH - ODE/DRARD

Search Terms:

Colonography - SUBJECT feels the FDA is not handling this issue well.

Allegations:

Sending proprietary documents and information out of the FDA. Some documents are may have the letter "K" followed by a string of six (6) numbers. Check to see if SUBJECT is sending these outside the FDA. Probably using Gmail to send out.

SUBJECT sent proprietary documents to press, possibly NY Times (Gartner Harris - sp?) - (Gardiner Harris - Corrected) for article alledging the FDA was mis-handling the Colonography topic.

His superiors believe HE is "ghost writing" his subordinates FDA reports. Check all possible avenues for possible occurances.

SUBJECT'S subordinates or co-horts:

[REDACTED]	DRL0091494
Paul T. Hardy	DRL0102315
Ewa Czerska	DRL0101046 DRL5125449
[REDACTED]	DRL0101600
Nancy Wersto	DRL5114924
Lakshmi Vishnuvajjala	DRL5125617 DRL0096322

Check all for possible POP3 or enternal, non-FDA email conversations, either via Websense, Encase, Mandiant, or Spector.

Interim RCS Report of Analysis & Findings

* Underlined items indicate findings post “Preliminary RCS Analysis Results.doc”

Allegation 1: Ghost Writing

- Indications of RCS receiving documents and email from co-workers / co-complainants pertaining to investigation via FDA email and Gmail
- Documents being edited by RCS and returned via Gmail – Mostly investigation related documentation.
- Lengthy suggestions of content to be used supplied by RCS via Gmail. These are contained in body of email for use by recipients (co-workers / co-complainants)
- Documents being edited by RCS and returned via Gmail – Identified Device Review documents/correspondence.
- Many of the above referenced documents and communications are currently going to JN for review/input.
- JN currently, heavily involved in communications regarding investigation

View All possible instances of the above allegation in order by date

Allegation 2: Supplying Internal Documents and Information to External Sources

- Multiple Gmail contacts with Gardiner Harris – NY Times
Identified multiple Gmail communications between RCS and Gardiner Harris regarding telephonic communications and in-person meetings

View All instances of the above noted in order by date

- Multiple Gmail contacts with Matthew Perrone – Associated Press News
Identified multiple Gmail communications between RCS and Gardiner Harris regarding telephonic communications and in-person meetings

View All instances of the above noted in order by date

- Multiple Gmail contacts with Alyah Khan – Inside Washington Publishers news organization
 - RCS Received internal document via Gmail from Kahn reference Chris Van Hollen – Alyah requested in same email not to be revealed as source or distribute document.

View All instances of the above noted in order by date

- RCS currently assisting Khan with editing story regarding Chris Van Hollen

View All instances of the above noted in order by date

- Kahn indicates the “editor” wants to hold the “Van Hollen story” as of May 14, 2010

View All instances of the above noted in order by date

- RCS and JN are in communication with Kahn regarding articles

View All instances of the above noted in order by date

- RCS and JN are in communication with Robert Lowes (Unknown News Org) may be an associate of Kahn's

View All instances of the above noted in order by date

- Multiple Gmail contacts with Joe Bergantino and Rochelle (unk last name) - RCN Cable Washington based Direct Cable provider)

Identified multiple Gmail communications between requesting times to meet and talk.

View All instances of the above noted in order by date

- RCS and JN received communication from Lainey Moseley – (Philadelphia Journalist of Unknown News Org) – Looking for a “Bigger Story” on CT scans, patient safety and FDA recommendations.

View All instances of the above noted in order by date

- Multiple Gmail contacts with Ned Feder (POGO – Project On Government Oversight – non affiliated non profit) – Emails include attachments with significant amount of documents.

View All instances of the above noted in order by date

- Multiple Gmail contacts with Jack Mitchell (aging.senate.gov) – Emails include attachments with significant amount of documents including those self-redacted.

View All instances of the above noted in order by date

- Multiple Gmail contacts with JN – Emails include attachments with significant amount of documents including those self-redacted

View All instances of the above noted in order by date

- Multiple Gmail contacts with Joan Kleinman (District Director for Rep. Chris Van Hollen) – Emails include attachments with significant amount of documents including those self-redacted.

View All instances of the above noted in order by date

Possible Future Concerns:

- Gmail from Paul Hardy stating “Time to pound them into dust – I think its time to talk to Joe about the documentary on Frontline” – Received May 11, 2010 - (Joe is an unknown person)

View All instances of the above noted in order by date

- Gmail correspondence indicating that Julian Nicholas has reapplied to CDRH and is being considered for a position.

View All instances of the above noted in order by date

Possible Potential Issue:

- Gmail correspondence with outside physician(s) - Possible FDA research knowledge being leveraged (ref CON and STARK) CSIRT not sure whether or not these are FDA internal projects.

View All instances of the above noted in order by date

- Image of Certificate of Remittance (transfer) from Shinan Bank dated 4/15/09 viewed on 4/26/2010

View All instances of the above noted in order by date

Possible Collaboration Issue:

- Numerous FDA emails and Gmail amongst primary and secondary actors indicating collaborative correspondence regarding review, editing, compilation, production or distribution of verbiage, documentation and information pertaining to medical reviews, current investigations, claims against HHS/FDA, and release of information to external organizations.

View All instances of the above noted in order by date

- Emails among Actors indicating a collaborative plan to produce a document defamatory to HHS/FDA that will be passed to Joan Kleinman, leaked to the press on Chris Van Hollen's letterhead and returned to Van Hollen's Office

View All instances of the above noted in order by date

- Email among Actors indicating a collaborative plan to modify document(s) to reflect only inconsistencies and remove any speculative information.

View All instances of the above noted in order by date

Actors List:

Primary Actors

1. Robert C. Smith – Medical Officer, CDRH, ODE/DRARD
WO66, RM0319G HFZ – 470, 10903 New Hampshire Ave, Silver Spring, MD
2. Paul T Hardy (also referred to as “PJ”) – Regulatory Review Officer, CDRH, OIVD
WO66, RM G309, 10903 New Hampshire Ave, Silver Spring, MD
3. Julian J. Nicholas – Former CDRH Physician

Summary – The above listed actors appear to be the point men. All communications amongst all the actors filter through one or all of these three primary actors. These actors appear to perform the majority of any review, editing, compilation, production or distribution of verbiage, documentation and information. Actors 1 and 3 appear to have the greatest involvement with media outlets and external organizations.

Secondary Actors

4. Ewa M. Czerska – Biologist, CDRH, ODE/DRARD
WO66, RMG322 HFZ – 470, 10903 New Hampshire Ave, Silver Spring, MD
5. [REDACTED] – Visiting Scientist, CDRH, OSEL/DIAM
WO62, RM3110, 10903 New Hampshire Ave, Silver Spring, MD
6. [REDACTED] – Biomedical Engineer, CDRH, ODE/POS/IDE
WO66, RM1643, 10903 New Hampshire Ave, Silver Spring, MD
7. Nancy Wersto – Biologist, CDRH, ODE/DRARD
WO66, RMG320, 10903 New Hampshire Ave, Silver Spring, MD
8. Lakshmi Vishnuvajjala – SUPV. Mathematical Statistician, CDRH, OSB/DBS/DDB
WO66, RM2208 HFZ – 550, 10903 New Hampshire Ave, Silver Spring, MD
9. [REDACTED] – Physicist, CDRH, ODE/DRARD
WO66, RMG308 HFZ – 470, 10903 New Hampshire Ave, Silver Spring, MD

Summary – The secondary actors listed above are in constant communication amongst themselves and the primary actors via FDA email, Yahoo Mail and Gmail. Communications involve review, editing, compilation, production or distribution of verbiage, documentation and information pertaining to medical reviews, current investigations, claims against HHS/FDA, release of information to the press and external organizations.

Ancillary Actors

10. Ned Feder – Staff Scientist / Writer – POGO (Project On Government Oversight)

1100 G Street, NW, Suite 900, Washington, D.C

11. [REDACTED] – Associate of Ned Feder
Nuclear Engineering, Texas A&M University
12. Jack Mitchell - United States Senate, Special Committee on Aging
G31 Dirksen or 628 Hart Senate Office Buildings, Washington, D.C.
13. Joan Kleinman – District Director, Congressman Chris Van Hollen (D-Md)
Office of Representative, 51 Monroe Street #507, Rockville, Md.
14. Congressman Chris Van Hollen (D-Md)
House of Representatives
1707 Longworth H.O.B., Washington, D.C.
District Office - 51 Monroe Street #507, Rockville, Md.

Summary – The ancillary actors above are actively participating with primary and secondary actors with regard to complaints and claims filed against HHS/FDA referencing FDA review / approval process, discrimination and hostility within the workplace. The above actors (with the exception of Congressman Chris Van Hollen and [REDACTED] directly) have received a substantial number of documents primarily from Actors 1 and 3. There has also been numerous communications with many of the secondary actors either directly or through the primary actors. References to one or more of the above ancillary actors providing a conduit to release information to the press has been identified.

Media Outlet Actors

15. Gardiner Harris – Reporter, New York Times
16. Matthew Perrone – Reporter, Associated Press
17. Alyah Khan – Reporter, Inside Washington Publishers news organization
18. Joe Bergantino – Reporter, RCN Cable Washington based Direct Cable provider
19. Rochelle (last name unknown) – Associate of Joe Bergantino
20. Lainey Moseley – Journalist, Unknown Philadelphia news organization - looking for a “Bigger Story” on CT scans, patient safety and FDA recommendations
21. Joe (last name unknown) – Documentaries, Frontline PBS (Public Broadcasting Service)

Summary – The media outlet actors listed above have actively and recently communicated primarily with Actor 1. Actor 1 has been in constant contact with Actors 15, 16, 17, & 18 via email, phone communications and/or in-person meetings regarding “issues with in the FDA”. Actor 20 was referred to Actor 1 by Actor 3. Actor 21 has been referenced to Actor 1 by Actor 2.